stable in the vessel, such that the filter has a tendency not to "tilt", which might result in less effective capturing of thrombus. Some vascular filters may be used in the vena cava, and may be described in such event as a "vena cava filter."

[0007] A vascular filter may be delivered through a catheter in a compressed shape, the filter tending to resiliently expand within a blood vessel and to retain the desired position and orientation. The vascular filter tends to trap thrombus or particles, and resist their movement further downstream. The filter includes, in a position of use, an outer shape corresponding to the internal diameter of the blood vessel, and one or more filter elements extending across the vessel.

[0008] In the temporal sense, there are three types of filters: (i) permanent filters, intended for permanent implantation; (ii) temporary filters, intended for removal within a time period; and (iii) retrievable filters, in which the physician has the option to implant the filter permanently or to remove the filter after some time. In the case of a retrievable filter, the filter may be designed so that the physician can choose whether to retrieve the filter at a later date, after the filter has been in place for a while. This way, the physician can evaluate the performance of the filter and the patient's condition, before deciding whether to retrieve the filter or not.

[0009] Regarding retrieval, one factor is "neointimalization" or in-growth of the vessel wall and tissue around the structural members of the filter. One type of neointimalization is endothelialization, which is the healing of the vessel inner surface by endothelial cells, and it is desirable to preserve these endothelial cells when removing a retrievable vascular filter. The improved designs of the present invention tend to minimize any impact during retrieval.

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[0010] Prior vascular filters have a demonstrated track record of filtering clots due to their filter basket design. However, because of the tendency of neointimal tissue to grow over the struts and other filter elements, may cause the filter to become mechanically interlocked with the tissue. When the tissue develops sufficient strength, the filter may no longer be retrievable. For some prior retrievable filters, this may occur somewhere between two and three weeks following implantation.

[0011] There may be several connection points where a filter may become interlocked with tissue, depending on the size of the vena cava or other body passage in which the device is placed. These include parallel struts between front and back filter baskets, at a shoulder or the filter basket, and at a diamond bifurcation.

[0012] According to the principles of the present invention, in order to retain the clot capturing capabilities of the filter baskets, these new filter baskets may be formed by laser-cutting a series of straight, parallel struts, and then shape-setting them in a way so that they closely resemble the filter baskets. As illustrated in the drawings, by forming the baskets from straight, parallel struts, all connections between struts are removed, so that the filter tends not to become interlocked with tissue.

[0013] The filter therefore may be retrievable for a longer time or possibly an indefinite period. It may also be desirable to have a filter which consists of two of these filter baskets, one caudal and one cranial, in order to prevent the filter from tilting. Further, in order to facilitate retrievability, it may also be desirable to connect both filter baskets in the middle, and for both filters to be sloped in the same manner as the caudal basket of the filter. In this manner, the outer legs of the filter can act as anchors to prevent migration of the filter.

[0014] This filter design provides the demonstrated clot capturing ability of the filter, but the filter elements are shaped from unconnected, straight parallel struts, which allow the filter to be removed from the tissue at a selected time without a tendency for affecting the vessel wall. This is because these struts are not physically connected to each other, and can separate during retrieval.

[0015] In addition, this type of filter is compatible with a bi-directional retrieval system. As shown in Figures 4 and 5, because the filter struts are not physically attached to each other, as is the case with prior filters, the catheter can be inserted through the windows of a filter flower basket, without risking entanglement of the catheter. If the retrieval catheter is inserted through one of the windows of the flower basket, the window of the flower basket can be opened, as shown in Figure 3, to allow the retrieval catheter to slip through.

[0016] It is also possible to change the filter basket by adding or subtracting even numbers of struts, so that the number of windows within the flower basket changes from six to five, seven, or some other number. It is also possible to change the direction that the flower baskets face. That is, the cranial basket can be oriented in the same direction as another basket on the filter.

[0017] A vascular filter along the lines of the present invention may provide several advantages, including effectively capturing thrombus while allowing blood flow, and resisting endothelialization of the filter. In other words, the filter enables a physician to have a longer time before choosing whether to retrieve a retrievable filter.

[0018] A vascular filter may have an initial compressed shape, in which the filter may have essentially a tubular shape, and may be contained in a lumen or passage defined by a catheter.

[0019] After a distal tip of the catheter reaches a desired site for treatment, a wire mandrel, plastic obdurator or other deployment device may be used to push the filter out of the catheter. And when the filter is released from the catheter, it tends to resiliently expand from the initial compressed shape to an expanded shape. When a vascular filter is retrieved from a blood vessel, the entire filter is resiliently compressed to a relatively small diameter, for extraction through a catheter.

[0020] The term "filter" will be used interchangeably, to refer to either (i) a combination device, including a resilient scaffold structure with more than one filter element, or (ii) those portion(s) of the scaffold which operate to capture thrombus.

[0021] The term "tubular" is used in its broadest sense, to encompass any structure arranged a radial distance around a longitudinal axis. Accordingly, "tubular" includes any structure that (i) is cylindrical or not, such as for example an elliptical or polygonal cross-section, or any other regular or irregular cross-section; (ii) has a different or changing cross-section along its length; (iii) is arranged around a straight, curving, bent or discontinuous longitudinal axis; (iv) has an imperforate surface, or a periodic or other perforate, irregular or gapped surface or cross-section; (v) is spaced uniformly or irregularly, including being spaced varying radial distances from the longitudinal axis; (vi) has any desired combination of length or cross-sectional size.

[0022] A vascular filter may include a first and second filter section, arranged on either side of a body section. The body section and the filter sections thus enclose a space. Due to the

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elongated shape of the vascular filter, and the arranging of the first and second filter sections on either side of the body member, the present filter may have an enhanced filtering effect. In other words, two opportunities have been created for intercepting thrombus moving inside the blood vessel.

[0023] A central tubular section tends to resiliently exert slight outward pressure along a large section of contact area on the blood vessel wall. Accordingly, the filter tends to exert some small amount of pressure on the internal wall of the blood vessel, and tends to hold itself in place. The vascular filter will consequently tend not to shift position. In addition, because of this elongated shape the vascular filter tends to center itself within the lumen, and not to rotate transversely or tilt over.

[0024] In an example, a vascular filter may be formed out of one single piece, which provides advantages including simplicity.

[0025] When viewed along the longitudinal axis of the filter, the filter sections may have the shape of a regular polygon, and thus may provide several smaller filtering "cells". The purpose of these filtering cells is to intercept thrombus moving inside the blood vessel, and the smaller filtering cells tend to capture more thrombus. All the cells may be of the same size, to provide a uniform filtering effect.

[0026] The filter sections, as arranged according to an embodiment described above on either side of the tubular body section, may be identical in shape, thereby enhancing the simplicity of the vascular filter according to the present invention.

[0027] It is of course possible to build various vascular filters according to the present invention, by various techniques and of various materials to obtain the desired features. It should be

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[0036] The drawings depict a vascular medical filter 10 along the lines of the present invention.

[0037] Filter 10 has an expanded shape, and an initial compressed shape. If filter 10 is delivered with a catheter and a pushing wire or mandrel or obdurator, filter 10 will have the initial compressed shape when it is within a passage or lumen of the catheter. In this configuration, the filter may have a tubular shape, and a pattern of struts or ribs may be affixed together or be made of a single piece of material with a series of cuts.

[0038] In any event, filter 10 tends to resiliently expand from the initial compressed shape to the expanded shape. Once the filter 10 is in the expanded shape, it tends to resiliently maintain that expanded shape, when deployed at a desired site for treatment within a body passage or vessel.

[0039] Filters of the present invention may be made with various manufacturing methods, including providing an initial tube, and then cutting a series of struts in the tube to enable expansion into the desired shape. Various other methods are of course possible, including forming the filter of discrete members and joining or connecting the members, or chemically etching a substrate. The manufacturing methods may include an inflatable or expandable mold, heating or cooling, welding, etc.

[0040] To clarify one possible method of making a filter, an initial tubular form defines a longitudinal axis and has first and second ends 14 and 16. More than one pair of struts 12 are cut in the tubular form, so as to define struts 12 extending between the first and second end 14 and 16; and the struts are treated so that they tend to resiliently expand from a compressed shape to an expanded shape. As shown in Figure 3, a central portion of each of the struts 12 is expanded in a radially outward direction, such that a gap is defined between the pairs of struts 12, and the individual struts 12 of each pair follow a

path which is substantially adjacent to the other strut 12 of that pair. In the drawings, six pairs of struts are shown, but of course any suitable number of strut pairs may be selected.

[0041] Next, a central portion of each of the struts is bent to follow an undulating path in the expanded shape, as shown in the second diagram of Figure 3 which is indicated by the arrow. Accordingly, in the expanded shape a first portion of each pair of ribs extends substantially adjacent to each other for a distance from the first end, and a second portion of each pair of ribs extends substantially adjacent to each other for a distance from the second end; wherein an intermediate portion of each one of a pair of ribs is bent to curve away from each other in the expanded shape.

[0042] Structurally, when viewed from the side in Figure 2, a filter in the expanded deployed shape has a central section 18, flanked by a first and second filtering section 20 and 22, which are flanked by the first and second end 14 and 16. The particular example depicted in the drawings is made from a single piece of tubular material, with a patterned series of cuts, which is treated to resiliently expand and form the filtering mesh structure. The filter structure could of course also be formed of multiple members which are affixed together.

[0043] The terms "filter" or "vascular filter" or "filtering" may be used in a broad or interchangeable fashion to refer generally to the entire filter 10, the first and second filtering section 22 and 24, the filtering effect on body fluids or particulates, or the results of such a filtering effect, or any other relevant aspect of the present invention.

[0044] While the filter 10 is implanted within a patient, body tissues naturally tend to incorporate or endothelialize implanted objects. This process of endothelialization may

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used to extract the filter 10 back into a catheter by means of a cooperating hook, snare or grabbing member.

[0047] In the compressed shape when the vascular filter is inside the catheter, the filter may include cuts extending in the longitudinal direction of the filter between, but not as far as, the ends of the filter. The cuts define strips of material as illustrated in the drawings. These strips expand to form the filtering first and second mesh, and the ribs. The specific cuts consequently also form the filter elements 20 and 22 on either side of the filter 10. The strips extend in a generally longitudinal direction in the compressed shape.

[0048] The vascular filter embodiment illustrated here may of course be used in the vena cava or any other desired site for treatment. The filter includes a number of ribs or struts extending in a generally undulating longitudinal direction. Liquid inside the blood vessel can pass through the vascular filter, but thrombus or particulates tend to be intercepted by one of the two filter sections 20 or 22.

[0049] As the filter sections 20 and 22 have been arranged on either side of the central body of the filter, a longitudinally symmetrical shape may be obtained (except for hook 24). In such a configuration, there is no difference whether the vascular filter is placed forward or backward inside the blood vessel. In other words, the proximal and distal ends of the filter may be identical and symmetrical. Accordingly, a single pre-loaded catheter system may be used to deploy a filter at a desired site, from either an upstream or downstream direction.

[0050] In the axial view of Figure 1, the filter sections on either side of the ribs of the vascular filters according to the present invention described above display diamond or polygon shapes. It is also possible to provide vascular filters of which the filter sections display in

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axial view a star shape, or any other suitable shape, as long as they successfully intercept blood clots or thrombus. An advantage of this feature is that, after passing the first filter section and the tubular section or the elongated body member, a second filter element for intercepting thrombus has been provided. Also, other shapes of the filter sections in axial view are possible, which shapes will occur to those skilled in the field after reading the present description. The shapes of the filter sections in axial view need not be symmetrical, and may in principle have any suitable appearance.

[0051] The filter may for example be delivered to the vascular region in the general area of the heart from either a femoral artery access point in the leg, or a jugular artery access point in the neck. Because the filter shown in Figure 2 may be longitudinally symmetrical, the same filter delivery system may be used for either femoral or jugular access.

[0052] Furthermore, retraction of a vascular filter according to the present invention is mentioned above, which should not limit the scope of the claims attached. Regarding the subject of the invention, it is therefore of no consequence whether the filter is placed permanently, in a removable manner, temporarily or otherwise.

[0053] Vascular filters according to the present invention may be made of any suitable material using a variety of methods. One material having the desired characteristics of strength, resilience, flexibility, biocompatibility and endurance is nitinol. Other possible materials include stainless steel and any other material having the desired properties.

[0054] A possible embodiment of the present invention is depicted in Figure 6, in which a filter 32 has a first and second filter section 34 and 36, connected by a central shaft 38. The filter elements 34 and 36 are formed of individual struts 40, which follow a curving path to define filtering cells with outermost point that are not connected. This "disconnected"

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